EXHIBIT 7

EXPERT REPORT OF MARK A. SCHUMACHER, M.D., Ph.D.

MARCH 25, 2019

and lobbied state and local government to remove barriers to broader use of opioids for the treatment of pain. ('Fueling an epidemic. Exposing the financial ties between opioid manufacturers and third party advocacy groups' 2018). A common feature across all of these efforts to promote the broader use of opioids was the message that the risk of addiction was rare, and the benefits of long-term opioid use were well established. These efforts were remarkably successful:

> An in-depth analysis of the promotion and marketing of OxyContin (Purdue Pharma, Stamford, CT), a sustained-release oxycodone preparation, illustrates some of the key issues. … OxyContin's commercial success did not depend on the merits of the drug compared with other available opioid preparations. The *Medical Letter on Drugs and Therapeutics* concluded in 2001 that oxycodone offered no advantage over appropriate doses of other potent opioids. Randomized double-blind studies comparing OxyContin given every 12 hours with immediate-release oxycodone given 4 times daily showed comparable efficacy and safety for use with chronic back pain and cancer-related pain. … In 2001 alone, the company spent $200 million in an array of approaches to market and promote OxyContin.
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> From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker-training conferences… Purdue promoted among primary care physicians a more liberal use of opioids, particularly sustained-release opioids. …
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> Purdue's promotion of OxyContin for the treatment of non–cancer-related pain contributed to a nearly tenfold increase in OxyContin prescriptions for this type of pain, from about 670 000 in 1997 to about 6.2 million in 2002… Prospective, randomized, controlled trials lasting at least 4 weeks that evaluated the use of opioids for chronic, non–cancer-related pain showed no consistent improvement in physical functioning. …
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> When OxyContin entered the market in 1996, the FDA approved its original label, which stated that iatrogenic addiction was "very rare" if opioids were legitimately used in the management of pain. In July 2001, to reflect the available scientific evidence, the label was modified to state that data were not available for establishing the true incidence of addiction in chronic-pain patients [and] also deleted the original statement that the delayed absorption of OxyContin was believed to reduce the abuse liability of the drug.
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> …Purdue funded more than 20 000 pain-related educational programs through direct sponsorship or financial grants, providing a venue that had enormous influence on physicians' prescribing throughout the country.

(Van Zee 2009). Evidence I have reviewed, including Defendants' internal communications, sales representative training materials and call notes, and promotional materials supports Dr. Van Zee's conclusions. A number of examples of this information are attached to my report as Exhibits A-C. These examples are not intended to be exhaustive, but, rather, illustrative of the Defendants' actions.

60. It is my opinion that as a result of direct-to-consumer and direct-to-physician marketing, as well as other efforts by opioid manufacturers to promote the widespread and long-term use of opioids, that the risk of addiction was trivialized, and the benefits of long-term opioid use overstated. Physicians were influenced by these efforts and a cautious and conservative approach to the use of opioids for the treatment of pain was replaced with much more liberal prescribing practices. I observed this firsthand in my own training after emerging from residency in 1995 to find increasing use of more potent formulations of opioids and sustained-release opioids for acute and chronic noncancer pain.

2. Specific misstatements designed to encourage physicians to overcome their reluctance to prescribe opioids liberally for chronic pain

61. Opioid manufacturers promoted chronic use of opioids based upon a set of key misrepresentations. These included the following: (1) taking long-acting opioids as prescribed for pain protects against addiction and abuse; (2) that new opioid formulations had no ceiling dose and were safe at high doses; and that (3) chronic opioid therapy improves function and quality of life. These misrepresentations appeared in print promotional materials and were also repeated by sales representatives in their direct marketing to physicians. In addition, (4) Purdue, at OxyContin's launch, took advantage of and was careful to maintain the perception that oxycodone is less potent than morphine, when in fact it is more potent.

a. Opioid manufacturers claimed taking long-acting opioids as prescribed for pain protects against addiction and abuse.

62. As discussed above, in 1996 when OxyContin was released, physicians generally were reluctant to prescribe opioids on a long-term basis because of fears of addiction. Purdue, of course, knew this through market studies that demonstrated this concern. Purdue admitted this when it pled guilty in 2007 to misbranding OxyContin:

> During the period February through March l995, PURDUE supervisors and employees obtained market research that included focus groups of forty primary care physicians, rheumatologists, and surgeons to determine their receptivity to using OxyContin for non-cancer pain. According to this market research, some of these physicians had concerns, similar to their concerns about combination opioids, regarding OxyContin's addictive potential and side effect profile, including that "[t]he biggest negative of [OxyContin] was the abuse potential."

See Agreed Statement of Facts, *United States. v. Purdue Frederick Co.*, No. 1:07-cr-00029 (W.D. Va. May 10, 2007) ("Purdue Guilty Plea") at §19. Internal documents produced in discovery confirm Purdue's knowledge of physicians' reluctance to prescribe opioids for non-cancer pain. *See* Exhibit C. For example, notes from a June 9-11, 1995 OxyContin Investigators' Meeting indicate that "among health care providers there is a perception that patients feel a 'stigma' associated with opioid analgesic therapy. Morphine and hydromorphone are most associated with this stigma. One of the patients' biggest fears appears to be the possibility of addiction…" PKY181823986 at 17 (*See* Exhibit C-2).

63. Sales representatives used multiple approaches to persuade physicians who expressed caution and concerns about the abuse and addiction potential of oxycodone and OxyContin. *See* Exhibit A. This amounted to repeated falsehoods that OxyContin / oxycodone had a decreased potential for addiction, was superior to and a less addictive alternate than combination forms of opioid analgesics containing hydrocodone (equal potency to morphine)

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